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## FEDERAL REGISTER

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Public Health Service National Toxicology Program; Chemicals (16) Nominated for Toxicological Testing: Request for Comments

**SUMMARY:** On July 15, 1982, the Chemical Evaluation Committee (CEC) of the **National Toxicology Program** (NTP) met to review 16 chemicals nominated for toxicological testing and to recommend the types of testing to be performed. CEC evaluation of nominated chemicals is an integral part of the NTP chemical nomination and selection process. With this notice, the NTP solicits public comment on the 16 chemicals listed herein.

**TEXT: SUPPLEMENTARY INFORMATION:** As part of the chemical selection process of the National Toxicology Program (NTP), nominated chemicals which have been reviewed by the NTP Chemical Evaluation Committee (CEC) are published with request for comment in the Federal Register and *NTP Technical Bulletin*. This enables outside individuals and groups to participate in the NTP evaluation process thereby helping the NTP to make better informed decisions as to whether to select, reject, or defer chemicals for testing.

Relevant comments and data submitted in response to this request are reviewed and summarized by NTP technical staff and then forwarded to the NTP Board of Scientific Counselors for its evaluation of the nominated chemicals and to the NTP Executive Committee for its decision making about testing. The NTP chemical selection process is summarized in the Federal Register, April 14, 1981 (46 FR 21828), and also in the NTP fiscal year 1982 Annual Plan, pages 137-319.

On July 15, 1982, the CEC evaluated 16 chemicals nominated to the NTP for toxicological testing. The table below lists each chemical, its Chemical Abstracts Service (CAS) registry number, and the types of testing recommended by the CEC.

Chemical	CAS No.	Committee Recommendation
1. (4,4'-Bithiazole)-2,2'-diamine	58139-59-6	<i>Salmonella</i> assay.
2. Butyl benzyl phthalate	85-68-7	Reproductive effects. Neurotoxicity. Carcinogenicity, including other chronic effects (rats only). (See below).
3. C.I. Basic Red 29	42373-04-6	<i>Salmonella</i> assay. <i>In vitro</i> cytogenetics. Cell transformation studies. Chemical analysis.
4. Cromolyn sodium	15826-37-6	No testing.
5. 5,6-Dichloro-2-benzothiazolamine	24072-75-1	<i>Salmonella</i> assay. Mouse lymphoma assay. Carcinogenicity.
6. N,N-Diethyl-4-((5-nitro-2-thiazolyl)azo)benzenamine	54289-46-2	<i>Salmonella</i> assay. Mouse lymphoma assay.
7. D-Fructose	57-48-7	No testing.
8. 2-Mercapto-4-methyl-5-thiazolyl methyl ketone	7725-93-1	<i>Salmonella</i> assay.
9. 6-Methoxy-2-benzothiazolamine	1747-60-0	Carcinogenicity.
10. 4-(6-Methyl-2-benzothiazolyl)benzenamine	92-36-4	<i>Salmonella</i> assay. Mouse lymphoma assay. <i>In vitro</i> cytogenetics. Subchronic testing.
11. 3-Methyl-5-isothiazolamine	24340-79-9	<i>Salmonella</i> assay. <i>In vitro</i> cytogenetics.
12. 2-Octyl-3-isothiazolone	26530-20-1	<i>Salmonella</i> assay. Mouse lymphoma assay.

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Chemical	CAS No.	Committee Recommendation
13. 5-Phenyl-2,4-diaminothiazole	490-55-1	No testing.
14. Thiabendazole	148-79-8 28558-32-9	No additional testing. (See below.)
15. 2-Thiazolamine	96-50-4	<i>Salmonella</i> assay. <i>In vitro</i> cytogenetics.
16. Thiazole	288-47-1	No additional testing. (See below.)

The NTP previously selected two of the 16 nominated chemicals for short-term mutagenicity testing, namely thiazole for testing in the *Salmonella* assay and thiabendazole for testing in the *Salmonella* and aneuploidy assays. Butyl benzyl phthalate was previously tested by the NTP for carcinogenicity, yielding negative results in mice of both sexes and equivocal results in female rats. The study was judged to be inadequate in male rats because of early mortality. The chemical was negative in the *Salmonella* assay and for chromosomal aberrations and sister chromatid exchanges in Chinese hamster ovary cells when tested by the NTP. Butyl benzyl phthalate has been selected by the NTP for testing in *Drosophila*. Additional toxicological studies of butyl benzyl phthalate have been scheduled in male F344 rats, namely a dermal absorption study, a six-month feeding study and dose dependent chemical disposition and metabolism studies. Following a complete analysis of the results of these studies, a carcinogenicity bioassay will be designed and initiated. This research was developed as part of the NTP testing initiative on phthalates.

Interested parties are requested to submit pertinent information. The following types of data are of particular relevance:

- (1) Completed, ongoing and/or planned toxicological testing in the private sector including detailed experimental protocols and, in the case of completed studies, resultant data.
- (2) Modes of production, present production levels, and occupational exposure potential.
- (3) Uses and resulting exposure levels, where known.
- (4) Results of toxicological studies for structurally related compounds.

Please submit all information in writing by (thirty days after date of publication). Any submissions received after the above date will be accepted and utilized where possible.

Dated: October 6, 1982.

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Director, National Toxicology Program.

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